J. Subpart K--Applicant and Enrollee Protections

In response to public comment, in this final rule, we relocated certain provisions involving applicant and enrollee protections to this new subpart K, "Applicant and Enrollee Protections." Specifically, we moved to this subpart certain provisions of proposed §457.902, which set forth definitions applicable to enrollee protections, proposed §457.985, which set forth requirements relating to grievances and appeals, and proposed §457.990, which set forth requirements for privacy protections. Public comments received on the relocated proposed provisions and changes made to them are discussed below.

To eliminate inconsistency and potential confusion, and in response to public comment, we decided to remove from the regulation text proposed at §457.995, which provided an overview of the enrollee rights provided in this part. Instead, we provide an overview of the enrollee protections contained throughout the part in the preamble to this final regulation. We respond below to the general comments on proposed §457.995, as well as to any general comments relating to the Consumer Bill of Rights and Responsibilities (CBRR). To the extent that a comment on proposed §457.995 relates to a specific enrollee protection provision cross-referenced in the proposed overview section, but located elsewhere than subpart I of the proposed regulation, we

responded to that comment earlier in this final rule in conjunction with comments and responses relating to that specific provision.

The most significant changes reflected in this subpart were made to the proposed "grievance and appeal" provisions at §457.985. Given the lack of clarity regarding the use of the terms "grievances" and "appeals," as noted by some of the commenters, we removed these terms from the final regulation. We opted instead, as we make clear in our responses to comments, to refer to the procedural protections required under this regulation as the "review process." We also note that in clarifying the scope and type of matters subject to review, we narrowed the range of matters subject to review from those defined in the proposed regulation. The minimum requirements for a review process identified in this regulation will apply only to separate child health programs, and States retain a significant amount of flexibility in designing their processes.

In this final regulation, a State is required to include in its State plan a description of the State's review processes and, pursuant to §457.120, to offer the public the opportunity to provide input into the design of the review process. We also clarify that matters involving eligibility and enrollment, on the one hand, and health services, on the other, are subject to

somewhat different review requirements. Core elements for a review process applicable to reviews of both types of matters; States may adopt their own policies and procedures for reviews that address these core elements. Such policies and procedures must ensure that -- (a) reviews are conducted by an impartial person or entity in accordance with §457.1150; (b) review decisions are timely in accordance with §457.1160; (c) review decisions are written; and (d) applicants and enrollees have an opportunity to--(1) represent themselves or have representatives of their choosing in the review process; (2) timely review their files and other applicable information relevant to the review of the decision; (3) fully participate in the review process, whether the review is conducted in person or in writing, including by presenting supplemental information during the review process; and (4) receive continued enrollment in accordance with §457.1170. Under the provisions of this final rule, a State could use State employees, including State hearing officers, or contractors to conduct the reviews, reviews could be conducted in person, by phone or based on the relevant documents, and a State could choose to use the same general process or different processes for reviews of eligibility and enrollment decisions and health services decisions.

With respect to enrollment matters, States must provide an applicant or enrollee with an opportunity for review of: (1) a denial of eligibility; (2) a failure to make a timely determination of eligibility; or (3) a suspension or termination of enrollment, including disenrollment for failure to pay cost sharing. States are not required to provide an opportunity for review of these matters if the sole basis for the decision is a change in the State plan or a change in Federal or State law (requiring an automatic change in eligibility, enrollment, or a change in coverage under the health benefits package that affects all applicants or enrollees or a group of applicants or enrollees without regard to their individual circumstances). For example, if a State amends its plan to eliminate all speech therapy services, a review would not be required if an individual appeals the denial of speech therapy. The final rules also establish that States must complete the review within a reasonable amount of time and that the process must be conducted in an impartial manner by a person or entity (e.g. a contractor) who has not been directly involved with the matter under review. For matters related to termination or suspension of enrollment, including a disenrollment for failure to pay cost sharing, the rules require that a State ensure the opportunity for continued enrollment pending the completion of the review.

As to adverse health services matters, a State must provide access to external review of decisions to delay, deny, reduce, suspend, or terminate services, in whole or in part, including a determination about the type or level of services; or of a failure to approve, furnish, or provide payment for health services in a timely manner. The external review must be conducted in an impartial and independent manner, by the State or a contractor other than the contractor responsible for the matter subject to external review. All reviews must be completed in accordance with the medical needs of the patient. The rules establish an overall 90-day time frame for external review, including any internal review that may be available. The rules also establish a 72-hour expedited time frame in the case where operating under the standard time frames could seriously jeopardize the enrollee's life or health or ability to attain, maintain or regain maximum function. In such situations, the enrollee has access to internal and external review, then each level of review may take no more than 72 hours. If the enrollee's physician determines the review should be expedited then it must be conducted accordingly, both for internal (if applicable) and external review.

In addition, we clarify the notice requirements at §457.1180, and require a State in §457.110(b)(6) to make

available to potential applicants, and provide to applicants and enrollees information about the review processes that are available to applicants and enrollees. The rules also require that States ensure that enrollees and applicants are provided timely written notice of any determinations required to be subject to review under §457.1130 that includes the reasons for the determination; an explanation of applicable rights to review of that determination, the standard and expedited time frames for review, and the manner in which a review can be requested; and the circumstances under which enrollment may continue pending review. Section §457.340(d) requires that in the case of a suspension or termination of eligibility, the State must provide sufficient notice to enable the child's parent or caretaker to take any appropriate actions that may be required to allow coverage to continue without interruption.

We provide States with flexibility under §457.1190 related to coverage provided through premium assistance programs to assure that all SCHIP eligible children have access to these enrollee protections, while recognizing States' reduced ability, or in some cases inability, to affect group health plan review procedures. This section provides that in States choosing to offer premium assistance programs, if the group health plan(s) through which coverage is provided are not found to meet the

review requirements of §§457.1130(b), 457.1140, 457.1150(b), 457.1160(b), and 457.1180, the State must give applicants and enrollees the option to obtain health benefits coverage other than coverage through that group health plan. The State must provide this option at initial enrollment and at each redetermination of eligibility.

1. Overview of Enrollee Rights (proposed §457.995).

In the proposed rule, we set forth in §457.995 an overview of certain enrollee rights that we provided throughout the proposed rule. In determining the scope of consumer protections to apply to separate child health programs, we considered the Secretary's statutory authority under title XXI and, within that authority, we attempted to balance the goal of ensuring consumer rights for SCHIP-eligible children with the need to afford States flexibility to design their separate child health programs. In this spirit, we proposed the enrollee protections listed in proposed §457.995 for enrollees in separate child health programs, and we also solicited public comments on how best to balance these interests in this regulation.

As noted above, while we removed proposed §457.995 from the regulation text in response to public comment, we respond to the general comments on proposed §457.995 below. We respond to comments on the specific provisions cross-referenced in the

§457.995 overview and contained in other subparts along with the responses to other comments on those cross-referenced provisions. For example, proposed §457.995 contains a cross-reference to §457.110 and the comments to proposed §457.995 also included comments on §457.110. We respond to the latter set of comments on §457.110 together with the other comments on §457.110. Below you will find our responses to the general comments on §457.995. Following our responses to general comments on this section is an overview of the enrollee protections provided in this final regulation.

Comment: One commenter suggested that HCFA either (1) consolidate all of the sections that relate to enrollee protections in one or two sections; or (2) leave the protections in different parts of the proposed rule, ensure that the protections are consistent with the CBRR, and provide a summary of the protections in the preamble only. While this commenter strongly supported HCFA's attempt to address the CBRR, the commenter believed that the proposed rule does not incorporate the rights and requirements in a logical fashion. They noted that §459.995 merely summarized requirements found in other sections of the rule, so it seemed redundant and, at times, inconsistent. According to this commenter, for example, §457.110(b) provided that information provided to enrollees must

be “accurate” and “easily understood” and that the information must be “made available to applicants and enrollees in a timely manner.” Proposed §457.995(a)(4), however, provided that “information must be accurate and easily understood and provide assistance to families in making informed health care decisions.” These two provisions addressed similar issues but included slightly different requirements, and this commenter argued that these inconsistencies are difficult to reconcile and therefore could result in inappropriate interpretations by States, courts, and enrollees. This commenter generally requested that HCFA reconcile the substantive requirements in other sections of the regulations with the requirements in §457.995(a) and (b).

The commenter also recommended that the provision relating to “assistance” include a reference to “application assistance” in §457.361(a) and to translation services. The same commenter suggested that HCFA correct the citations referenced in §457.995(a)(3). A different commenter noted that there is no §457.735(c), and the reference in §457.995(b) to §457.735(c) should instead be to §457.735(b). One commenter also suggested that HCFA divide §457.995(c) regarding access to emergency services into two separate sections: “access” and “cost sharing for emergency services.”

Response: We agree with the comments about the inconsistency between §457.995 and certain other substantive sections of the regulation. As noted above, to avoid confusion, we removed proposed §457.995 from the regulation text and provide an overview in the preamble of the enrollee protections provided throughout the regulation. As for the comments about the cross-references and the need to address certain issues separately, we made every effort to ensure that the cross-references in the final regulation are correct and that issues are adequately addressed in the regulation provisions and explained in the overview now provided in the preamble.

Comment: Many commenters expressed support for HCFA's decision to incorporate the CBRR provisions in the proposed regulations. One commenter specifically noted that the rights to apply for assistance, to have applications processed in a timely manner, to be informed about benefits, participating providers and coverage decisions, and to have access to a fair process to resolve disputes are basic consumer protections that are critical to ensuring that the program's promise of health care coverage becomes a reality. Another commenter supported the recognition of consumer protections relating to emergency services, participation in treatment decisions, and respect and nondiscrimination. One commenter expressed support for HCFA

offering States a good deal of flexibility in the application of these requirements.

Response: We appreciate the support expressed by the commenters.

Comment: Several commenters believed that HCFA exceeded its statutory authority in applying the CBRR to title XXI regulations. Several commenters recommended deleting section §457.995 because, in their view, there is no basis for implementation of the CBRR in title XXI and, in many cases, States already have Patient Bill of Rights laws. One commenter noted that children in Medicaid expansion programs will be covered under consumer protections available in Medicaid, while children in separate child health programs will be covered under State consumer protection laws. One commenter suggested that, where a conflict exists, or similar requirements are imposed by State law, State law should prevail. This same commenter urged HCFA to consider a "substantial compliance" process in these instances. Several other commenters added that they support protecting health care consumers, but that, in their view, requiring the States to implement specific consumer protections for SCHIP could have additional fiscal and administrative impact on their programs.

Response: In establishing the applicant and enrollee protections, we did not simply import the CBRR. We considered our statutory authority, the nature and scope of State laws that might apply to separate child health programs, the need for minimum consumer protection standards, and the States' authority under title XXI to design their own program consistent with the requirements of Federal law. There is statutory authority under title XXI for each enrollee protection included within this final regulation as outlined in the overview and set forth in this part. We describe the statutory authority for each of the enrollee protections in the preamble to each proposed section containing an enrollee protection, in the "Basis, Scope, and Applicability" regulation section of each subpart containing one of the enrollee protections, and often in our responses to the specific comments on the sections or subparts of the proposed rule containing the enrollee protections. While we removed §457.995 from the regulation text, this was done for clarity and to promote consistency, and does not reflect any change in our position regarding the statutory authority for the cited enrollee protections.

States are required to ensure that enrollees in separate child health programs are afforded the minimum consumer protections set forth in this regulation. These minimum

protections set a framework within which States may design their procedures consistent with applicable State laws, and we believe it will not be difficult to ascertain whether Federal or State law prevails. If a contractor serving enrollees in a separate child health program is subject to State consumer protection law that is more prescriptive in the areas addressed in this regulation, then in complying with State law, the contractor will comply with this Federal regulation as well. For example, if a State law requires the completion of its review processes for certain health services decisions within a shorter time frame than does this regulation, the State will comply with both Federal and State law when it complies with the shorter State-required time frame. On the other hand, if the Federal time frame requirement is shorter, the Federal requirement will prevail. We have set specific time frames in only a limited number of circumstances to establish the outer boundaries of an efficient and effective system that accomplishes the purpose of the Act. Given the scope of the flexibility afforded States under these rules, we expect that the instances where these Federal rules will impose more stringent standards than those imposed by State law, in those States with an applicable State law, will be limited. In addition, the processes by which certain disputes are resolved are left completely to States'

discretion; in such cases, State rules will control. By requiring that a State delineate review procedures in its State plan, we expect the State plan development process, including public notice and comment, will promote State-specific approaches to designing review procedures that reflect local issues and accommodate the State's administrative structure, while ensuring minimum protections to applicants and enrollees.

We will work with States to resolve any questions that might arise in a particular State. No additional compliance process will be instituted beyond that which is already established in subpart B of part 457 under the authority of section 2106(d)(2) of the Act, which requires States to comply with the requirements under title XXI and empowers HCFA to withhold funds in the case of substantial noncompliance with such requirements.

As for the fiscal impact of these requirements, we do not believe that the costs need to be large relative to the cost of services provided to enrollees. The protection of enrollee rights is a critical component of program costs for the provision of child health assistance. States retain broad flexibility to design and implement efficient and effective review processes. Because these regulations do not prescribe any particular review process, States have the flexibility to rely on other already established State review processes for the purpose of resolving

disputes that arise in the context of their separate child health programs.

Comment: One commenter noted that, in the preamble to the proposed regulation, we cited a Presidential directive on the CBRR as justification for imposing requirements on State child health plans. This commenter believes that this justification was not sufficient because the proposal conflicted with Executive Order 13132 provisions limiting federal agencies from unnecessarily limiting State flexibility. This commenter expressed the view that HCFA lacks authority to impose the CBRR upon the States to the extent that the CBRR contradicts Congress' unambiguous intent when enacting title XXI and to the extent that it conflicts with E.O. 13132. In this commenter's view, title XXI was designed to provide flexibility to the States in creating and implementing SCHIP programs, and requires the States to *describe* to HCFA the different aspects of the State plans with minimal restrictions. This commenter argued that, although Congress adopted a general approach intended to allow States to design and experiment with their programs, HCFA has applied the CBRR to remove States' flexibility, and has brought the CBRR to bear most heavily on States that exercised that flexibility. This commenter asserted that a State should be able to tailor its own program to achieve the broad goals of the CBRR and should be

able to do so by innovative means tailored to the needs of its population. In this commenter's opinion, we could "cure" the regulation (1) by eliminating proposed §§457.985, 457.990 and 457.995; and, more importantly, (2) by evaluating each separate program on its own terms.

Response: As noted above, there is statutory authority for each applicant and enrollee protection outlined in the overview and set forth in this part. In considering how to develop applicant and enrollee protections for this regulation generally, we attempted to balance the important goal of ensuring consumer rights for the SCHIP-eligible population with the flexibility afforded States under title XXI to design their separate child health programs, and we have also considered the value of enrollee feedback through the review process in ensuring compliance with program requirements. In all instances, we have based our regulations on the provisions of title XXI. In our view, the final regulations comply with title XXI and are consistent with the CBRR and E.O. 13132. The regulations establish minimum standards and offer States the opportunity to design their own systems and procedures consistent with these standards. This final regulation does not require a uniform system for providing basic protections to children and their

families but rather recognizes and permits significant State-by-State variation.

Comment: One State expressed concern that the level of detail of the CBRR provisions in the proposed regulation severely limits States' flexibility in contracting and hampers their ability to adjust contract provisions that are not working well. Another commenter stated that HMOs and insurers would be less likely to participate in SCHIP if they have to implement both the State requirements and the requirements within the proposed rule, which may have conflicting language.

Response: We appreciate the commenters' concerns and have taken the comments into account in these final regulations. In order to provide all applicants and enrollees the protections established by these regulations pursuant to title XXI, it is essential for contracts to reflect the provisions in this final regulation. However, while we included several important protections within this regulation, we also omitted other details and protections provided by the CBRR, to allow States to design their own review procedures and to minimize any conflict with applicable State law. States have flexibility in the design and implementation of applicant and enrollee protections and we are available to provide technical assistance to States and to facilitate discussions among States as they develop or revise

contracts so that they comply with the final regulations. We will also share information about successful State practices among the other States.

Comment: One commenter recommended that HCFA use national standards in applying the principles outlined in the CBRR, such as the Standards on Utilization Management and Member Rights and Responsibilities of the National Committee for Quality Assurance (NCQA). This commenter believed that a standardized system reduces administrative complexity and cost and is more likely to benefit all managed care enrollees. The commenter recommended that the final rule include provisions that allow States to adopt other systems that comport with the BBA and HCFA's Quality Improvement Standards for Managed Care objectives (QISMC), subject to review and approval by HCFA.

Response: We appreciate the recommendation for using the standards issued by NCQA, a private organization that accredits managed care entities, on Utilization Management and Members Rights and Responsibilities. We encourage States to explore such models as a means to develop and implement high quality processes that protect applicant and enrollee rights in a comprehensive manner. While there are advantages to a standardized system, we considered such models and opted to develop minimum standards and permit States the ability to adopt or vary from such models, as

long as the standards established by the final regulations are met.

Comment: Several commenters suggested that a provision be added to §457.995 to require States to include in their managed care contracts provisions that implement all relevant State laws in the area of managed care consumer protections. One of these commenters believed that State law protections should apply to State contracts with entities arranging for the delivery of care that might not be licensed insurance carriers.

Response: While we recognize the importance of the managed care consumer protections contained in many States' laws, we do not require that the contracts comply with State consumer protection laws applicable to certain health plans. The inclusion of such protections in SCHIP contracts is a matter of State law. To the extent that a managed care entity or entity that contracts with a State in connection with its SCHIP program is subject to State insurance or business laws, the entity would be required to comply with applicable State law. We encourage States to include in their contracts with health plans, or other organizations, the applicable patient protections required under State law to the extent they do not conflict with the standards in this regulation.

Comment: One commenter suggested that this overview section also list enrollees' rights to linguistic access to services. This commenter recommended that the preamble explain these rights and provide examples, such as providing bilingual workers and linguistically appropriate materials that include recommendations on how States and contracted entities can comply. Another commenter requested that cultural competency and linguistic accessibility requirements be incorporated throughout the provisions on information, choice of providers and plans, access to emergency services, participation in treatment decisions, respect and nondiscrimination, and grievances and appeals.

Response: We addressed these comments in subpart A along with other comments on §§457.110 and 457.130 involving compliance with civil rights requirements and the linguistic appropriateness of information provided to enrollees.

Overview of Applicant and Enrollee Protections in Final Regulation

In this final rule, we require States to provide certain protections for applicants and enrollees in separate child health programs. Outlined below are the protections afforded under this regulation.

- Information Disclosure

Section 457.110 provides that States must make accurate, easily understood, linguistically appropriate information available to families of potential applicants, applicants, and enrollees and provide assistance to families in making informed health care decisions about their health plans, professionals, and facilities. In addition, this section that families be provided information on physician incentive plans as required by the final regulation at §457.985. We also require, at §457.65(b), that a State must submit a State plan amendment if it intends to eliminate or restrict eligibility or benefits, and that the State certify that it has provided prior public notice of the proposed change in a form and manner provided under applicable State law, and that public notice occurred before the requested effective date of the change.

Under §457.350(g), we require States to enable families whose children may be eligible for Medicaid to make informed decisions about applying for Medicaid or completing the Medicaid application process by providing information in writing on the Medicaid program, including the benefits covered and restrictions on cost sharing. Such information must also advise families of the effect on eligibility for a separate child health program of neither applying for Medicaid nor completing the Medicaid application process. Finally, §457.525 provides that the State

must make a public schedule available that contains the following information: current cost-sharing charges; enrollee groups subject to the charges; cumulative cost-sharing maximums; mechanisms for making payments for required charges; and the consequences for an applicant or enrollee who does not pay a charge, including the disenrollment protections required in **§**457.570.

! Choice of Providers and Plans

The rules provide enrollees with certain protections regarding choice of providers and plans through §§457.110 and 457.495. Section 457.110 provides that the State must make accurate, easily understood, linguistically appropriate information available to families of potential applicants, applicants, and enrollees, and provide assistance to families in making informed health care decisions about their health plans, professionals, and facilities. Section 457.495 provides that, in its State plan, a State must describe its methods for assuring: 1) the quality and appropriateness of care provided under the plan particularly with respect to well-baby, well-child and adolescent care, and immunizations; 2) access to covered services, including emergency services as defined at §457.10; 3) and appropriate and timely procedures to monitor and treat enrollees with chronic, complex, or serious medical conditions,

including access to specialists experienced in treating the specific medical condition; and 4) that decisions related to the prior authorization of health services are completed in accordance with the medical needs of the patient, within 14 days of the receipt of a request for services.

- Access to Emergency Services

Sections §§457.410(b), 457.515(f), 457.555(d), and 457.495 address the right to access emergency services. Section §457.10 defines “emergency medical condition” and “emergency services” using the “prudent layperson” standard recommended by the President’s Advisory Commission and adopted by many States in their consumer protection laws. Section 457.410(b) requires that regardless of the type of health benefits coverage offered under a State’s plan, the State must provide coverage for emergency services as defined in §457.10.

Under §457.555(d), for targeted low-income children whose family income is from 101 to 150 percent of the FPL, the State may charge up to twice the charge for non-institutional services, up to a maximum amount of $10.00, for services furnished in a hospital emergency room if those services are not emergency medical services as defined in §457.10. Under §457.515(f), States must assure that enrollees will not be held liable for cost-sharing amounts beyond the co-payment amounts specified in

the State plan for emergency services provided at a facility that does not a participate in the enrollee's managed care network. Section 457.495(b) provides that in its State plan, a State must describe its methods for assuring the quality and appropriateness of care provided under the plan particularly with respect to access to covered services, including emergency services as defined at §457.10.

! Participation in Treatment Decisions

This regulation gives enrollees in separate child health programs the right and responsibility to participate fully in treatment decisions. Under §457.110, the State must make accurate, easily understood, linguistically appropriate information available to families of potential applicants, applicants and enrollees and provide assistance to families in making informed health care decisions about their health plans, professionals, and facilities. The State must also make available to applicants and enrollees information on the amount, duration and scope of benefits and names and locations of current participating providers, among other items. In addition, under §457.985, States must guarantee that its contracts for coverage and services comply with the prohibition on interference with health care professionals' advice to enrollees, requirement that professionals provide information about treatment in an

appropriate manner, the limitations on physician incentive plans, and the information disclosure requirements related to those physicians incentive plans referenced in that provision. We also require under §457.110(b)(5) that the State have a mechanism in place to ensure that information on physician incentive plans, as required by §457.985, is available to potential applicants, applicants and enrollees in a timely manner. We also provide under §457.130 that the State plan must include an assurance that the State will comply with all applicable civil rights requirements, including title VI of the Civil Rights Act of 1964, title II of the Americans with Disabilities Act of 1990, section 504 of the Rehabilitation Act of 1973, the Age Discrimination Act of 1975, 45 CFR part 80, part 84, and part 91, and 28 CFR part 35.

! Civil Rights Assurances

In §457.130, we require in the State plan an assurance that the State will comply with all applicable civil rights requirements, including title VI of the Civil Rights Act of 1964, title II of the Americans with Disabilities Act of 1990, section 504 of the Rehabilitation Act of 1973, the Age Discrimination Act of 1975, 45 CFR parts 80, 84, and 91, as well as 28 CFR part 35. These civil rights laws prohibit discrimination based on race, sex, ethnicity, national origin, religion, or disability.

- Confidentiality of Health Information

The regulations address this right in §457.1110, which provides privacy protections to enrollees in separate child health programs. Under that section, the State must ensure that, for medical records and any other health and enrollment information maintained with respect to enrollees (in any form) that identifies particular enrollees; the State and its contractors must establish and implement certain procedures to ensure the protection and maintenance of this information.

- Review Process

Sections 457.1130(b) and 457.1150(b) provide that enrollees in separate child health programs must have an opportunity for an independent external review by the State or a contractor, other than the contractor responsible for the matter subject to external review, of a decision by the State or its contractor to delay, deny, reduce, suspend, or terminate health services, in whole or in part, including a determination about the type or level of services; or for failure to approve, furnish, or provide payment for health services in a timely manner. Section 457.1160(b) sets a time frame under which this process must occur, including an expedited time frame in the case where an enrollee’s life or health or ability to attain, maintain or regain maximum function are in jeopardy.

2. Basis, scope, and applicability §457.1100.

This subpart interprets and implements section 2101(a) of the Act, which provides that the purpose of title XXI of the Act is to provide funds to States to enable them to initiate and expand the provision of child health assistance to uninsured, low-income children in an effective and efficient manner; section 2102(a)(7)(B) of the Act, which requires that the State plan include a description of the methods used to assure access to covered services, including emergency services; section 2102(b)(2) of the Act, which requires that the State plan include a description of methods of establishing and continuing eligibility and enrollment; and section 2103, which outlines coverage requirements for a State that provides child health assistance through a separate child health program. This subpart sets forth minimum standards for applicant and enrollee protections that apply to separate child health programs.

3. Definitions and use of terms (selected provisions of proposed §457.902).

Below we will address the comments on the definitions in proposed §457.902 and terms used in proposed §457.985 that relate to the applicant and enrollee protections set forth in this new subpart K.

In proposed §457.902, we defined contractor as “any individual or entity that enters into a contract, or a subcontract to provide, arrange, or pay for services under title XXI of the Act. This definition includes, but is not limited to, managed care organizations, prepaid health plans, primary care case managers, and fee-for-service providers and insurers.” As stated in the preamble to the proposed rule, we defined the term contractor in proposed §457.902 because it is used most significantly in reference to accountability for ensuring program integrity. However, we also used the term in proposed §457.985 relating to grievances and appeals. Because the term is now used in subparts I and K, we moved the definition of contractor to §457.10. We retained the definition of contractor set forth in the proposed regulation. We defined the term “grievance” in proposed §457.902 as “a written communication, submitted by or on behalf of an enrollee in a child health program, expressing dissatisfaction with any aspect of a State, a managed care or fee-for-service entity, or a provider’s operations, activities or behavior that pertains to – (1) the availability, delivery, or quality of health care services, including utilization review decisions that are adverse to the enrollee; (2) payment, treatment, or reimbursement of claims for health care services; or (3) issues unresolved through the complaint process

established in accordance with §457.985(e)." In the preamble to the proposed rule, we indicated that we "defined the term 'grievance' to provide some context into the section requiring States to have written procedures for grievances and appeals." We defined the term grievance to be consistent with the proposed Medicaid managed care regulations, and to give the States the opportunity to utilize the process that is already in place for the Medicaid program.

As noted earlier, we are now referring to the procedural protections afforded to applicants and enrollees in separate child health programs under this regulation as a "review process." Because the term grievance is no longer used or needed in our provisions regarding the review process, we removed the definition from the regulation text.

Comment: One commenter noted that there is a definition of the term "grievance," but no definition of the term "appeal." Another commenter proposed that we delete the definition of grievance. Several commenters recommended that HCFA ensure that the terms "grievance" and "appeal" are employed consistently across all programs, including Medicare, Medicaid and SCHIP; these commenters expressed confusion about different uses of the terms "grievance," "appeal" and "complaint" in these other programs. One commenter also questioned whether the reference to

§457.985(e) was intended to be to §457.985(d). This commenter recommended that it would be clearer for HCFA to use the terminology used in the proposed Medicaid managed care regulations. Another commenter argued that federal requirements for resolving enrollee complaints and grievances will reduce plan participation because many plans will not be willing to have separate processes for SCHIP enrollees that exceed existing State statutory requirements.

Response: Consistent with our modified approach to requirements in this area, under which we give States flexibility in how they choose to handle many types of disputes, we removed the definition of "grievance" from the regulation text. We are now referring to the procedural protections afforded to enrollees in separate child health programs under this regulation as a "review process." Therefore, we did not add a definition of "appeal." We rectified the incorrect cross-reference noted by the commenter in removing the definition of grievance from the regulation text. We agree that, to the extent that we intend to impose Medicaid requirements, we should use the same terminology. In this regulation, however, we determined not to require States to adopt the Medicaid approach to review processes, but we did attempt to use consistent terminology as appropriate.

In order to assure the fair and efficient operation of SCHIP and to ensure that children eligible for coverage under separate child health programs have access to the health care services provided under title XXI, these final rules establish minimum consumer protection standards for applicants and enrollees in separate child health programs balancing a recognition that State law varies in this area with the need to assure certain protections to all children, regardless of where they live. If a contractor serving separate child health program enrollees is subject to State consumer protection law that is more prescriptive in the areas addressed by this regulation, then the contractor, in complying with State law, will comply with this Federal regulation as well.

Comment: Several commenters believed the term "contractor" as used in §457.985(a) is too broad. One commenter said the definition appeared to include every fee-for-service physician that serves a participant in a separate child health program. According to this commenter, this rule makes such a physician's decision to provide Tylenol instead of an antibiotic subject to a grievance procedure. The commenter noted that this policy may discourage physician participation in the program and recommended that the statement exclude those providers to whom the enrollee is not "locked in" or whom the enrollee is not otherwise required

to utilize. One commenter noted that inconsistency in the use of "participating contractors" in §457.995(g)(1) and "participating providers" in §457.985(a) resulted in confusion. Another commenter believed that the term "participating providers" as used in §457.985(a) needed to be clarified because "providers" are generally defined as health care professionals, agencies or institutions. It was also not clear to this commenter why "health providers" would be included in this directive. If the term intended was contractors, in the view of this commenter, §457.985(a) should be amended. If another meaning is intended, the commenter recommended that it be added to the definitions at §457.902.

Response: We intended to include in the term "contractor" any individual or entity that would enter into a contract with a State to furnish child health assistance to targeted low-income children. As reflected in §§457.1130(b) and 457.1150(b), we believe enrollees must have an opportunity for an independent, external review of a determination to delay, deny, reduce, suspend, or terminate health services, in whole or in part, including a determination about the type or level or services; or for failure to approve, furnish, or provide payment for health services in a timely manner. This right applies whether or not the actions mentioned were taken by a State directly or by a

contractor. Because we believe that we accomplish this goal with the definition as proposed, we did not modify the definition of contractor. We agree that we created confusion by using "participating contractors" and removed §457.995(g)(1) and its reference to "participating contractors" from the regulation text. We also agree that we created confusion by using the term "participating providers" and not defining it. Our intent was to ensure that applicants and enrollees receive written notice of decisions that they have the opportunity to challenge through a review process. In §457.1180, we did not use the term "participating providers," and clarified that a State must assure that applicants and enrollees receive timely written notice of any determinations subject to review under §457.1130. This could be accomplished, for example, by requiring contracting managed care entities to provide notice either directly or through a provider serving as an agent of that entity.

4. Privacy protections §457.1110 (proposed §457.990).

We proposed that the State plan must assure that the program complies with the title XIX provisions as set forth under part 431, subpart F--Safeguarding Information on Applicants and Recipients. Moreover, we proposed that the State plan must assure the protection of information and data pertaining to

enrollees by providing that all contracts will include guarantees that:

- Original medical records are released only in accordance with Federal or State law, or court orders or subpoenas;
- Information from or copies of medical records are released only to authorized individuals;
- Medical records and other information are accessed only by authorized individuals;
- Confidentiality and privacy of minors is protected in accordance with applicable Federal and State law;
- Enrollees have timely access to their records and to information that pertains to them; and
- Enrollee information is safeguarded in accordance with all Federal and State laws relating to confidentiality and disclosure of mental health records, medical records, and other information about the enrollees.

We proposed that State child health plans are subject to any Federal information disclosure safeguard requirements as well as requirements set forth by their State regarding information disclosure, including use of the Internet to transmit SCHIP data between and among the State and its providers. We also proposed that electronic transmission of data to HCFA must comply with HCFA's policies and requirements regarding privacy and

confidentiality of data transmissions. Data transmissions between providers, health plans, and the State would be subject to these requirements. Finally, we proposed to provide that the State must assure that the program will be operated in compliance with all applicable State and Federal requirements to protect the confidentiality of information transmitted by electronic means, including the Internet.

Comment: One commenter strongly supported the inclusion of the Medicaid privacy protections for all SCHIP enrollees and the listed contract requirements regarding information protection and access for enrollees.

Response: We appreciate the commenter's support for the inclusion of the specific language relating to the Medicaid provisions, and we have retained this requirement in the final rule. As for the listed contract requirements regarding information protection and access for enrollees, we have modified slightly our requirements in the final rule. Specifically, we are requiring that for medical records and any other health information maintained with respect to enrollees that identifies particular enrollees, States and their contractors must abide by all applicable Federal and State law regarding confidentiality and disclosure; maintain records and information in a timely and accurate manner; specify the purpose for which information is

used and disclosed; and except as provided by Federal or State law, ensure that enrollees may request and receive a copy of their records and request that information be supplemented or corrected. To minimize potential inconsistencies with other Federal regulations, we have removed the specific references to safeguarding electronic data transmissions, including the use of the Internet to transmit SCHIP data. Similarly, we have eliminated the language requiring safeguarding of information because subpart F of part 431 already includes such a requirement. We also clarify that original medical records and other identifiable information must be offered the same level of protection under this rule. These revisions should not be interpreted as a reduction in privacy protections. The protections addressed by the commenter will be afforded to SCHIP applicants and enrollees in separate child health programs, consistent with any other applicable law.

Comment: Two commenters supported the provision requiring that the State plan must provide that all contracts will include guarantees that protect the confidentiality and privacy of minors, subject to applicable Federal and State law. One commenter noted that both State and Federal law contain a variety of provisions that protect the confidentiality of minors. According to this commenter, minor consent statutes in every

State accord minors the right to give their own consent for services and often provide confidentiality protection for minors as well. Another commenter believed that confidentiality is critical to ensure that adolescents seek health care services, particularly those related to reproductive health. Both adolescents and providers consistently identify concerns about confidentiality as a major obstacle to health care for adolescents. This commenter urged HCFA to encourage States to ensure that all information, including statements explaining benefits related to reproductive health services and family planning, is provided to enrollees in a confidential manner.

Response: We appreciate these commenters' support. The final rule requires States to abide by all applicable Federal and State laws regarding confidentiality and disclosure, including those laws addressing the confidentiality of information about minors and the privacy of minors, and privacy of individually identifiable health information.

Comment: One commenter recommended that HCFA explain in the preamble language how these privacy protections interact with the privacy standards proposed in October 1999 and the security standards proposed in August 1998. This commenter believed that it is extremely important that all of the protections are harmonized so that the legal interpretations of State and

contractor obligations are not unnecessarily confusing. Other commenters noted that the SCHIP protections should be consistent with the rulemaking on Standards for Privacy of Individually Identifiable Health Information (**Federal Register**, November 3, 1999).

One commenter expressed general concern about what they viewed as the lack of consistency across the federal government and the States regarding privacy standards. The commenter noted that dual regulation increases compliance costs, which are ultimately passed on to enrollees and consumers. This commenter specifically suggested that §457.990(b) be deleted and replaced with a requirement that the State health plan must assure the protection of information and data pertaining to enrollees by providing that all contracts contain identical privacy protections as required under current federal Medicaid contract requirements. If this change was not acceptable, the commenter had alternative suggestions. The commenter first noted that the term “authorized individuals” is not defined in §457.990(b)(2) and §457.990(b)(3) and suggested that clarification is necessary to ensure that this definition includes all parties needing access to enrollee information for treatment, administration, payment, health care operations and other appropriate purposes consistent with Medicaid standards. Second, this commenter

suggested the need to clarify in §457.990(b)(5) that enrollees' right to access information pertaining to them falls under the Federal Privacy Act of 1974.

Response: We agree with the need to harmonize the SCHIP privacy requirements and other Federal privacy law and policy, and as a result have made several changes to this section. In revising §457.1110, we examined the proposed Medicaid Managed Care regulation (63 FR 52022), the proposed Medicare+Choice regulation (63 FR 34968), and the proposed requirements set forth under the authority of the Health Insurance Portability and Accountability Act (HIPAA). Additionally, we acknowledge the commenters' point that "authorized individuals" was not defined and have deleted it from the final regulations so as not to conflict with Federal or State law addressing permissible disclosures. We also elected not to specify particular Federal or State laws in the final regulation (in order to clarify that we intend to require that States follow all applicable Federal and State laws, including laws and regulations not yet finalized or developed).

Comment: One commenter recommended that HCFA review the American Academy of Pediatrics policy statement, "Privacy Protection of Health Information: Patient Rights and Pediatrician Responsibilities" (*Pediatrics* Vol. 104 No. 4, October 1999).

Response: We appreciate the suggestion that we review the Academy's report, and in our review found that it provided useful information regarding patient rights and pediatrician responsibilities from the Academy's perspective. We encourage providers and others to review the report for additional information on complying with aspects of Federal and State privacy law. For the purposes of this regulation, however, we attempted to harmonize the privacy requirements for separate child health programs with other applicable Federal law, and opted not to adopt additional measures.

Comment: One commenter expressed that §457.995(f) is awkward in that it excludes confidentiality protections and access rights afforded by other laws, such as local or tribal laws, as well as industry practices that are more protective of confidentiality and provide greater access to health information. This commenter recommended removing the words "only" and "federal and State law" from §457.995(f) so that it reads: "States must ensure the confidentiality of a enrollee's health information and provide enrollees access to medical records in accordance with applicable law (§457.990)."

Response: As noted above, we removed §457.995(f) from the regulation text. We considered this comment, however, with respect to proposed §457.990(b)(1), (b)(4), and (b)(6). We did

not intend the proposed privacy protections to preclude greater local or tribal protections or protections of enrollee access to information. However, depending upon the applicable Federal or State law, it is possible that local or tribal protections could be preempted if the Federal or State law in questions requires a preemption.

Comment: One State indicated that its separate child health program uses a premium assistance program under which it would not contract for health services and therefore would not have a mechanism to enforce the proposed privacy requirements. The State indicated that the mechanism available to impose these requirements is the State Insurance Code, and recommended it be recognized.

Response: States are required to ensure that enrollees in separate child health programs are covered by the minimum privacy protections defined under §457.1110 of this regulation, regardless of what model is used to deliver services under a separate child health program funded with Federal SCHIP funds. If the premium assistance program is subject to State insurance law that requires the minimum privacy protections consistent with those set forth by this regulation, then the State will be in compliance with this requirement. If a group health plan participating in the State's premium assistance program does not

comply with the minimum privacy requirements set forth in this regulation, then the State may not provide SCHIP coverage to separate child health program enrollees through that group health plan.

5. Review processes §§457.1120-457.1190 (proposed §457.985).

In the proposed rule, we provided that the State and its participating providers must provide applicants and enrollees written notice of the right to file grievances and appeals in cases where the State or its contractors take action to: (1) deny, suspend or terminate eligibility; (2) reduce or deny services provided under the State's benefit package; (3) disenroll for failure to pay cost sharing. In addition, proposed sections §§457.365, 457.495, and 457.565, respectively, required that §457.985 apply in these specific circumstances. In §457.361(c), we proposed to require that the State must send each applicant a written notice of the decision on the application and if eligibility is denied or terminated, the specific reason or reasons for the action and an explanation of the right to request a hearing within a reasonable amount of time.

We further proposed in §457.985(d) that the State must establish and maintain written procedures for addressing grievances and appeal requests, including processes for internal review by the contractor and external review by an independent

entity or the State agency. We proposed that these procedures for grievances must comply with the State requirements for grievances and appeals that are currently in effect for health insurance issuers (as defined in section 2791(b) of the Public Health Service Act) within the State. We proposed that procedures must include a guarantee that the grievance and appeals requests will be resolved within a reasonable period of time.

We also proposed that States may elect to use the grievance procedures as described in part 431, subpart E regarding fair hearings for Medicaid applicants and recipients, and the Medicaid grievance and appeal procedures for Medicaid managed care entities, which were set forth in the Medicaid Managed Care proposed rule (63 FR 52022).

We further proposed to require that the States and their contractors must have in place a meaningful process for reviewing and resolving complaints that are submitted outside of the grievance and appeals procedures as part of the quality assurance process.

In addition, we proposed at §457.985(e) that the State must guarantee, in all contracts for coverage and services, enrollee access to information related to actions which could be subject to appeal in accordance with the “Medicare+Choice” regulation at

§422.206, which prohibits “gag rules” and protects enrollee-provider communications, and §422.208 and §422.210, which address limitations on physician incentive plans and requirements for information disclosure to enrollees related to those plans.

Following are responses to comments on proposed §457.985.

Comment: One commenter suggested reorganizing §457.985 into a more logical format to keep all of the grievance sections in one subpart, with cross-references as appropriate.

Response: We agree with this comment and made appropriate changes to the regulation text to consolidate provisions relating to the review process. In this final regulation, we moved proposed §457.985(a),(b),(c), and (d) relating to review procedures from subpart I to subpart K, and further revised and clarified these sections.

We retained subparagraph (e) related to provider-enrollee communications and limits on physician incentives as the whole §457.985 in subpart I. In addition, to improve clarity and to be responsive to comments, we revised that section.

Sections §§457.1120 - 457.1190 are the provisions of the final regulation that represent the reworking of proposed §457.985. Subpart K now contains most of the provisions relating to the review process, and related provisions in other subparts

were revised or deleted as appropriate, to be consistent with the provisions of subpart K.

Comment: Many commenters noted that the lack of minimum standards may cause lengthy time periods for completion of grievance and appeals processes, leaving many enrollees without needed benefits. The commenters believed that, despite the difficulties in establishing a grievance and appeals system that addresses the needs of States, participating contractors, Medicaid, and SCHIP, consistency between the Medicaid and SCHIP procedures is integral to ensuring ease of administration for providers and quality care for enrollees. The commenters noted that because enrollees may transfer between Medicaid and SCHIP at different times, consistency in the application of grievances and appeals processes would eliminate confusion. The commenters recommended that HCFA establish a set of minimum standards the States and participating providers must meet when providing services to enrollees.

Response: In finalizing this regulation, we attempted to strike a balance between State flexibility and enrollee protection consistent with the provisions and framework of title XXI. Rather than requiring Medicaid grievance and appeal requirements for separate child health programs, we adopted core elements for a review process under §457.1140, and minimum

standards for impartial review, under §457.1150, that States with separate child health programs must meet. We also included, under §457.1160, specific time frames for review of health services matters and a requirement that review of eligibility and enrollment matters be completed within a reasonable amount of time. We also required, in both cases, that States consider the need for expedited review in appropriate circumstances. We recognize that enrollees will often move between the two programs, and we encourage States to standardize the review processes to the extent possible and rely on Medicaid procedures when it is advisable to do so. In §457.110, we also require that States notify potential applicants, applicants and enrollees of the procedural protections afforded to applicants and enrollees under the separate child health program. This information should help ease transition between Medicaid and separate child health programs, to the extent that a State chooses to implement different review systems.

Comment: Several commenters believed that grievance and appeal rights are inappropriate for title XXI. Likewise, one commenter believed that SCHIP is not an entitlement program and should not be subject to the grievance procedures required for entitlement programs. In the view of this commenter, HCFA has exceeded its statutory authority in applying the CBRR to the

title XXI regulations. One commenter recommended deleting §457.985 because, in their view, there is no basis for the development of Federal grievance or appeal processes in title XXI, and expressed that States should have the flexibility to develop and apply processes consistent with State law. Another commenter recommended also deleting §457.365 because they believed we had exceeded our authority, and recommended that in the final rule a reference to all eligibility actions (denial, suspension, and termination) be incorporated in §457.361(c).

Response: We acknowledge that a separate child health program may be quite different from a State's Medicaid program, and the final regulation does not require States to comply with the Medicaid requirements for grievance and appeal procedures. However, we believe that States operating separate child health programs under title XXI need to establish a review process and comply with minimum standards. While title XXI provides States with a great deal of flexibility, section 2101(a) of the Act provides that the "purpose of the title is to provide funds to States to enable them to initiate and expand the provision of child health assistance to uninsured, low-income children in an effective and efficient manner." As we asserted in the preamble to the proposed rule, review processes that meet certain minimum standards are essential components of State programs in order to

assure that child health assistance is provided in an effective and efficient manner.

Moreover, section 2102(b)(2) requires that a State plan include a description of methods "of establishing and continuing eligibility and enrollment." Procedures to address adverse determinations related to eligibility or enrollment are necessary for ensuring accurate assessments of initial and ongoing eligibility. Section 2102(a)(7)(B) requires a State in its State plan to describe methods used "to assure access to covered services." This section supports our requiring minimal standards for a review process designed to ensure that eligible children have access to covered services, including an expedited review process when there is an immediate need for health services. Section 2103 also requires a specific scope of coverage, and provides the authority for the provisions of the final regulation that seek to assure that a meaningful review process is in place to enforce that access requirement. In the final regulation, eligibility actions and procedural protections related to such actions are described in §§457.1130(a), 457.1140, 457.1150(a), 457.1160(a), 457.1170, and 457.1180.

Comment: Several commenters believed States should be allowed to use existing appeal mechanisms for managed care. One commenter noted opposition to Federal requirements that would

force the States to alter standard commercial plan contracts(for example, specific appeals criteria or procedures), and urged HCFA to allow States to develop appeals and grievance procedures that are consistent with State insurance regulations. Another commenter noted that under New York law, Child Health Plus enrollees are granted broad grievance and utilization review rights, as well as external appeal rights for certain determinations. These rights are set forth in detail in the member handbook or contract, and whenever services under the program are denied as not medically necessary, individuals are advised of their appeal rights. This commenter supported allowing States to use existing procedures in lieu of "Medicaid-style" procedures. One commenter noted that such an approach is more efficient and that a separate grievance process would be problematic because the costs of it would be subject to the 10 percent administrative cap.

Response: As noted above, we do not require any particular type of review process. States have discretion under these rules to design their own review process and we fully expect that such procedures may vary from State to State while still operating consistent with the requirements adopted here. We recognize, however, that our review process requirements might necessitate changes in standard commercial contracts if such contracts are

used in separate child health programs. However, we believe that these changes are likely to be minimal given the broad discretion left to States to establish their review procedures. The regulations provide a minimum level of protection to applicants and enrollees in separate child health programs. To the extent that the State health insurance law on reviews is more stringent than, but also complies with, these requirements and the State or its contractor is subject to that State health insurance law, these rules will not impose any new requirements on States or their contractors. We believe that title XXI ensures that enrollees enjoy some minimal procedural protections regardless of the State in which they reside.

Comment: Several commenters believed that HCFA should clarify that States with separate child health programs have flexibility in setting up appeals processes to determine what appeals are submitted to whom, and do not need to use the Medicaid procedures. For example, the commenters asked for clarification that, if a State uses the health plan or another appeals body for its review process, the State can have grievances sent directly to that entity.

Response: While the use of Medicaid fair hearing procedures for a separate child health program may be efficient for some States as it may eliminate the need for two parallel, and to some

extent, duplicative processes, the use of Medicaid procedures is not required in a separate child health program. States may determine the structure of their review process as long as it complies with the minimum standards of this regulation. In order to alleviate any confusion created by the language of proposed §457.985(c), which noted that States have the option to adopt the Medicaid procedures, we removed that language from the final regulation text.

Comment: One commenter believed that HCFA should clarify that States that have implemented Medicaid expansions must provide applicants and recipients all of the Medicaid protections.

Response: To clarify, States that implement Medicaid expansions must provide applicants and enrollees all of the Medicaid protections. Subpart K only applies to separate child health programs.

Comment: One commenter was concerned about the grievance procedures proposed in the Medicaid managed care regulations. The commenter was concerned about the meaning of the term “complaint;” obligations to submit the decision and case file to the State agency; issues arising from the State fair hearing process; the obligation of a managed care entity to issue a notice of intended action; administrative issues regarding how

the organization handles complaints and grievances; and continuation of benefits obligations pending appeal.

Response: This commenter's concerns relate to the final regulation for Medicaid managed care, and are beyond the scope of this regulation. We direct interested parties to review the Medicaid managed care final rule, once published, for issues related to Medicaid managed care. Again, subpart K only applies and relates to separate child health programs.

Comment: One commenter requested that HCFA clarify whether a State that has existing laws relating to consumer protections is able to choose its Medicaid procedures instead. A different commenter suggested that the proposed regulations could be read to suggest that HCFA anticipates that States will use both the Medicaid procedures and procedures applicable to commercial health plans. However, this commenter noted that many States do not have the same grievance rules for Medicaid and for commercial health plans, so it may be impossible for managed care entities to meet both sets of requirements. This second commenter assumed that HCFA intended that the use of Medicaid procedures and procedures applicable to commercial health plans would be alternatives, and recommended that HCFA clarify this issue.

Response: As noted above, the use of Medicaid procedures may be efficient for States, but those procedures are not

required. State laws applicable to commercial plans may or may not apply to a separate child health program, depending on the provisions of the State law. We expect that States that decide to adopt Medicaid procedures for the review process in their separate child health program will thereby be meeting State law requirements applicable to commercial health plans. However, this rule only establishes core elements and minimum standards for reviews; it does not require States to adopt Medicaid review procedures.

Comment: A few commenters proposed giving States three options to comply with requirements for grievance and appeals procedures: 1) processes that comply with the State grievance and appeal procedures currently in effect for health insurance issuers; (2) the Medicaid rules, systems and procedures; or (3) the Health Carrier External Review Model Act as developed by the National Association of Insurance Commissioners (NAIC).

Response: We appreciate the suggestion on possible models. However, rather than mandating a specific, detailed model that States must follow, we elected instead to establish core elements and minimum standards that reflect the most important aspects of these and other models of patient protection, but give States flexibility over the design of their review process. States can elect to use any model as long as that model addresses each of

the core elements and meets or exceeds the minimum requirements set forth by this regulation.

Comment: One commenter supported internal review by the contractor and external review by an independent agency (or the State agency) for appeals related to eligibility, premiums and benefits. Another commenter questioned HCFA's requirement for external and internal review.

Response: We appreciate the support expressed by one of these commenters and acknowledge the diverging opinions on the value of internal and external reviews. In this final regulation, we address external review only, and only with regard to adverse health services matters. Under §457.1130(b) of this final regulation, we require that a State ensure that an enrollee has the opportunity for external review of a decision by the State or its contractor to delay, deny, reduce, suspend, or terminate health services in whole or in part, including a determination about the type or level of services; or for failure to approve, furnish, or provide payment for health services in a timely manner. Under §457.1150(b) we require that States must provide enrollees with the opportunity for an independent, external review that is conducted either by the State or a contractor other than the contractor responsible for the matter subject to external review. States retain the flexibility to

determine whether, how, and when to require internal review of these decisions and other kinds of decisions and actions. As for decisions relating to eligibility and disenrollment for failure to pay cost sharing, as described below, a review process that meets core elements outlined in §457.1140, and applicable standards of §§457.1150-1180, will meet the standards set by these regulations. We note that under §§457.1150(a), we require that a review of an eligibility or enrollment matter as described in §457.1130(a), must be conducted by a person or entity who has not been directly involved in the matter under review. This could be a State agency or an independent contractor employed by the State to assist with making eligibility determinations. The State may decide to use the same review process for reviews of eligibility and health services or different process at its discretion.

Comment: One commenter believed that the grievance and appeal system must be designed to provide enrollees with a single point of entry so that, regardless of the subject matter, enrollees file their grievances or appeals with a single State entity. The entity would then be responsible for assigning it to the appropriate reviewing authority.

Response: We recognize the importance of easy and clear access to the review process. In §457.110(b)(6), we require

States to make available to potential applicants, and to provide to applicants and enrollees information on the review process. We also require States to describe the core elements of their review process in their State plans, in part to assure that the public has input into the design of the review process. A single point of entry may be an efficient way to manage the process, particularly if the State decides that different entities will be responsible for reviewing health services and eligibility decisions. However, a single point of entry for the review process is not required by this final regulation.

Comment: One commenter expressed their view that the rules lack sufficient clarity and specificity to ensure that consumers will be accorded adequate due process protections in a State that does not adopt the Medicaid procedures. Accordingly, in this commenter's view, HCFA should outline the basic requirements that must be addressed by a State if it does not choose the Medicaid system. At a minimum, this commenter suggested that these requirements should specify: (1) the content of the written notice; (2) circumstances for continued benefits; (3) processing of grievances and fair hearings including exhaustion requirements; (4) the enrollees' rights and responsibilities during the grievance and fair hearing process; (5) standards for

conduct of the hearing; and (6) time frames for expedited and final resolution of grievances and appeals.

Several commenters underscored the need for due process protections in title XXI because of the lack of entitlement to benefits under the program and recommended requiring the Medicaid procedures. One commenter suggested that families need full access to an impartial review process, timely and adequate notices, opportunities to review records and evidence and examine witnesses, the right to represent themselves or to bring a representative, the right to receive a decision promptly, and the right to prompt corrective action. According to this commenter, referencing State laws without applying specific standards will be inadequate to assure equitable treatment of children because some of the laws are loose and vague on matters such as the time period within which a grievance must be resolved, who must hear the appeal, and what notice must be provided.

Another commenter considered it inappropriate to allow States with separate child health programs to use less stringent appeal procedures than required under Medicaid. In the commenter’s opinion, SCHIP benefits are targeted at low-income children who, like Medicaid eligibles and recipients, have limited resources. The commenter also noted that while SCHIP is not an entitlement, constitutional due process considerations may

apply and require that recipients be afforded minimal protections. If this is the case, the commenter noted that HCFA's current proposed rule may not meet those standards.

Response: We agree with these commenters about the need to set forth minimum standards for procedural protection for States with separate child health programs and provide these protections in §§457.1120 through 457.1190 of the final regulation. We adopted many of the commenters' suggestions in these sections of the final regulation, consistent with basic principles of due process. We did not elect to issue requirements for exhaustion of an internal review process, opting instead to require external review of health services matters as described in §457.1130 and setting maximum time frames for the completion of external review (and internal, if available) in §457.1160(b). It is within each State's discretion whether and in what conditions internal review will be available. The requirement is that the external review be implemented within 90 days (taking into account the medical needs of the patient). If a State chooses to establish internal review, internal and external review must be completed within that time frame.

We also left to the State's discretion enrollee responsibilities during the review process, although the regulations do set forth basic enrollee rights in §457.1140.

Many of the other protections suggested by the commenters have been addressed throughout §§457.1120-457.1180. In these sections, we identify basic procedural protections that are common to most review procedures and that must be provided in the context of separate child health programs. However, in the interest of preserving State flexibility, we left many of the particular design elements related to implementing the protections to the State's discretion.

Comment: One commenter noted that clarification is needed with regard to which types of decisions are subject to which grievance and appeals processes.

Response: We acknowledge the need for clarification about the scope of the requirements relating to review processes and provide it in the final regulation at §457.1130.

Comment: One commenter noted inequity in the fact that Medicaid expansion programs receive 75 percent FMAP for grievance and appeal activities while separate child health programs are required to pay for these activities within the 10 percent limit for administrative expenditures.

Response: As the commenter indicated, section 2105(c)(2) of the Act places a limit on administrative expenditures. The costs of a review process are subject to the enhanced matching rate under SCHIP and may or may not be considered administrative costs

that fall under the 10 percent administrative cap, depending on the nature of the expenditure and the method by which it is paid. While there is no cap on administrative expenditures within Medicaid, such expenditures consume far less than 10 percent of Medicaid spending. To the extent that a State relies on preexisting review mechanisms, such as those that may be operating under the State's insurance laws, the State's employee health plan or it's Medicaid program, further efficiencies may be realized.

Comment: Several commenters noted the need to include grievance or appeal protections for providers who contract with SCHIP managed care entities or with SCHIP programs on a fee-for-service basis. In the opinion of these commenters, such protections are necessary because many of these "safety net" providers cannot afford to have payments withheld, delayed or denied without an expedited process to challenge the actions of the managed care entity or SCHIP program. One State did not support the requirement that providers be given a notice of appeal.

Response: We agree that States need to adopt procedures to address these concerns, but did not include in the proposed regulation or incorporate in this final regulation a requirement that States adopt procedural protections for providers involved

in disputes with a State or a contractor. Providers and their advocates may work at the State level to obtain such protections, which States have the flexibility to provide.

Comment: Several commenters recommended that the regulation require that bilingual workers and linguistically appropriate materials used in application assistance, including information relating to grievances and appeals, be made available to ensure that all applicants, including those with limited English proficiency and persons with disabilities (parents and guardians with disabilities) are given notice and understand their rights concerning eligibility. Commenters recommended that the preamble explain the title VI mandate requiring linguistic access to services and give examples of how States and contracted entities can comply. Two commenters asked that both the preamble and regulations make it clear that failure to provide linguistically and culturally appropriate notices and services is grounds for filing a grievance or appeal.

Response: We addressed these comments in subpart A along with other comments on §457.110 and §457.130.

Comment: One commenter on §457.365 noted that the grievance and appeal provisions depend almost entirely on the ability of families to know about and comprehend the nature of the rights available. According to this commenter, organizations upon which

families rely for information should be utilized in a family-friendly manner.

Response: In §457.110 we set forth requirements regarding the availability of accurate, easily understood, linguistically appropriate information for potential applicants, applicants, and enrollees, including information about the review process. We also encourage organizations working with enrollees to provide appropriate assistance to enrollees' families in accessing and navigating the review processes in the State. Additionally, under §457.1140(d)(1), we require that States provide applicants and enrollees with the opportunity to represent themselves or have representatives of their choosing in the review process.

! State plan requirement §457.1120 (proposed §457.985(b)).

Proposed §457.985(b) required States to establish and maintain written procedures for addressing grievances and appeals. We received many comments to subpart A noting the need for more routinized public input into the development of the State plan. In order to ensure public input into the development of the grievance and appeal procedures and ensure that each State addresses the core elements as it designs its procedures, the final regulations require a State to describe its review process in its State plan, pursuant to §457.1120. We believe that the combination of State flexibility, minimum Federal standards, and

public input will produce systems that provide necessary and appropriate procedural protections without imposing a “one size fits all” approach.

! Matters Subject to Review §457.1130 (proposed §§457.361(c), 457.365, §457.495, 457.565, 457.970(d), 457.985(a)).

Eligibility and Enrollment Matters

In §457.361(c), we proposed to require that States provide an applicant whose eligibility is denied or an enrollee whose enrollment is terminated with an explanation of the right to request a hearing. In proposed §457.985(a)(1) and (2), we proposed to require that States give applicants and enrollees written notice of their right to file grievances and appeals in cases where the State takes action to deny, suspend, or terminate eligibility, or to disenroll for failure to pay cost sharing. Section 457.365 of the proposed regulation provides that a State must provide enrollees in separate child health programs with an opportunity to file grievances and appeals for denial, suspension or termination of eligibility in accordance with §457.985. Likewise, §457.565 of the proposed regulation provided that a State must provide enrollees in separate child health programs with the right to file grievances and appeals as specified in §457.985 for disenrollment from the program for failure to pay cost sharing. In §457.970(d), we proposed that a State may

terminate the eligibility of an applicant or enrollee for "good cause" other than failure to continue to meet the requirements for eligibility. We also provided that enrollees terminated for good cause must be given a notice of the termination decision that sets forth the reasons for termination and provides a reasonable opportunity to appeal the termination decision.

Comment: One commenter indicated that since title XXI is not an entitlement, and therefore children are not entitled to receive services, States should not be required to establish a grievance procedure for children terminated for good cause.

Response: As provided by §457.1130(a), States must provide enrollees in a separate child health program with an opportunity for a review of a termination of eligibility. The opportunity for a review is an important component of a fair and efficient system that should apply regardless of whether a State believes that it terminated coverage for good cause. Indeed, in such a situation, the purpose of the review would be to allow the enrollee an opportunity to address whether there was good cause to terminate eligibility. Reviews serve an important purpose regardless of whether the coverage provided is considered to be an entitlement. In this final regulation, we removed proposed §457.970(d) (concerning "good cause") because we found it unnecessary and the comments suggested it was potentially

confusing. States have the flexibility to identify any number of reasons for terminating an enrollees's eligibility that are consistent with this regulation.

Comment: A few commenters believed that denials, suspensions, and terminations of eligibility should be reviewed under a different process than the internal and external review process set out in §457.985(b). Several commenters also questioned the appropriateness of utilizing the envisioned grievance and appeals system for decisions regarding failure to pay cost sharing and noted that disenrollment for failure to pay cost sharing should be reviewed under a different process than that set out in §457.985. One commenter suggested that HCFA require States to use their Medicaid grievance and fair hearing process for eligibility and disenrollment determinations rather than deferring to internal appeals or State-specific insurance practices.

Response: We agree with the comment that internal and external review consistent with State insurance law may not be the appropriate form of review for eligibility and enrollment matters, but we leave this matter to State discretion, as long as the minimum review requirements are met. A State may use the same process for reviewing eligibility and enrollment decisions as it uses to review health services decisions, or it may use

different processes as long as the requirements pertaining to each type of review are met.

Comment: One commenter suggested that HCFA permit applicants and enrollees to file grievances and appeals on the grounds that eligibility determinations were limited or delayed.

Response: We agree that an enrollee should be given the opportunity for a review to address the failure to make a timely eligibility determination. Section §457.1130(a) requires a review to address such a situation. As for the case of a limitation of eligibility, we believe that denials, reduction, or terminations of eligibility encompass and therefore require an opportunity for review of a decision to limit eligibility.

Comment: One commenter believed that HCFA should modify its regulations to allow reasonable exceptions to grievance requirements, such as when disenrollment or suspension of services results from a State exceeding its allotment.

Response: Under §457.1130(c), we provide an exception and do not require a State to provide an opportunity for review of an adverse eligibility, enrollment, or health services matter if the sole basis for the decision is a provision in the State plan or in Federal or State law that requires an automatic change in eligibility, enrollment, or a change in coverage under the health benefits package that affects all applicants or enrollees or a

group of applicants or enrollees without regard to their individual circumstances. If a State stopped enrolling new applicants because it had spent all of its allotted funds, this would likely be a situation where applicants would not need to be granted a review of the denial of their application. Whether a review would be required would depend on whether the denial was automatic and applied broadly. For example, if a State with limited funds amended its approved State plan to enroll only new applicants with special health care needs, an opportunity for review would be required to provide denied applicants an opportunity to establish that they met the State's enrollment criteria. However, if a State exceeds its allotment and no longer wishes to operate its State plan as approved, the State could either keep the plan in place and, pursuant to the State plan, suspend operation of the program until the beginning of the next Federal fiscal year when additional funding becomes available, or request withdrawal of its State plan by submitting a State plan amendment to HCFA as described in §§457.60 and 457.170. Under each of these scenarios, the State would no longer be approving any new applications and as such, reviews of application denials or suspensions would not be subject to the review requirements.

Health Services Matters

In §457.985(a)(3), we proposed to require the State to provide the right to file grievances and appeals in cases where the State or its contractors take action to "reduce or deny services provided for in the benefit package." In addition, proposed §457.495 required States to provide enrollees in a separate child health program the right to file grievances or appeals for reduction or denial of services as specified in §457.985.

We note that the range of health services-related matters required to be subject to review under the final rule is more narrow than the range of matters included within the definition of grievance in the proposed rule.

Comment: Several commenters agreed with the inclusion of §457.985 in the proposed rule but encouraged modification of the provision to include the right to file a grievance or appeal for the termination of services as well as for reduction or denial of services in whole or in part.

Response: We agree with this comment, and §457.1130(b)(1) of the final rule reflects that States must ensure that an enrollee has an opportunity for external review of matters related to delay, denial, reduction, suspension, or termination of health services, in whole or in part, including a determination about the type or level of services.

Comment: A commenter suggested that HCFA should permit applicants and enrollees to file grievances and appeals on the grounds that requests for covered services were limited or delayed.

Response: We agree with the comment, and in §457.1130(b)(2), we require States to ensure an enrollee has an opportunity for external review of a failure to approve, furnish, or provide payment for health services in a timely manner.

Comment: One commenter noted that the system of review to an independent body should resemble the Medicaid system to the extent possible, in order to ease the burden on providers and to provide continuity for families who move between programs.

Response: We recognize the importance of easing the burden on providers and on families who move between a separate child health program and Medicaid. However, we decided not to require that the external review for separate child health programs mirror the external review process required under Medicaid and to take a more flexible approach consistent with title XXI. We note that some States have chosen to adopt the Medicaid model for reviews in order to have a consistent system of review for their child health programs.

Comment: One commenter indicated that States should provide a timely appeals process that includes direct discussion between

the reviewing panel, the patient's physician and the relevant specialists and, if appropriate, an external review by an independent panel of pediatricians experienced in the treatment of the patient's illness.

Response: We agree with the need for a timely process. Under §457.1140(b), review standards must be timely in accordance with the time frames set forth under §457.1160. However, under this final regulation, we have not prescribed the type of communication that must be allowed between the enrollee's physician and any review panel. The State has the leeway to require consultation with the enrollee's provider and/or with independent physicians, within the framework of the minimum standards established by these rules.

Comment: One commenter believed that §457.985(d) should be deleted because the term "complaint" is not defined and it is not clear what type of problem constitutes a complaint that would end up outside the grievance and appeals processes. The commenter noted that it is also unclear who would be responsible for making such a determination, and what would happen should the plan decide that a consumer's grievance is really only a "complaint," or vice versa. In this commenter's view, the regulation should not sanction the development or utilization of "complaint" systems that fall outside of the grievance and appeals process.

Response: We have deleted proposed §457.985(d) from the regulation text because we agree that its provisions were unclear. Under the final regulation, we decided only to require external review of the types of matters described in §457.1130(b) and to leave States and their contractors the flexibility, within the confines of applicable law, to design review procedures to address any decisions or actions not required to be subject to review under the final regulation.

! Core Elements of Review §457.1140

Comment: One commenter asserted that HCFA should specify the basic components of a fair hearing, that the State agency responsible for administering the separate child health program, rather than a managed care plan, should retain responsibility for eligibility and enrollment appeals, and that the preamble should encourage States to use the Medicaid fair hearing process for appeals of this kind. According to this commenter, a fair hearing requires the following components: (1) the right to an impartial hearing officer; (2) the right to review records that will be used at the hearing; (3) the right to review evidence and examine witnesses; (4) the right to represent oneself or be assisted by another; and (5) the right to obtain a timely written decision with an explanation of the reasons for the decision. One commenter specifically questioned the rationale for external

review of eligibility decisions because those decisions do not require the medical judgement necessary in benefit denials.

One commenter argued that HCFA should adopt minimum standards for States that opt not to use their Medicaid fair hearing processes to ensure that: (1) appeals and determinations are timely; (2) decisions are made by an impartial hearing officer or person; (3) hearings are held at reasonable times and places; and (4) enrollees have a right to: (a) timely review their files and other applicable information necessary to prepare for the hearing; (b) be represented or represent oneself; and (c) present testimony and evidence.

Response: While we agree that a State agency review, such as the Medicaid hearing process, may be more appropriate for eligibility and enrollment matters than an internal and external review process developed under an insurance model for health services matters, we determined it was not appropriate to require a State agency review or the Medicaid process for separate child health programs. Instead, these final regulations establish a set of core elements that each State must address when it designates its review process.

Section §457.1140 incorporates certain suggestions of commenters and requires that States, in conducting a review, ensure that:(a) reviews are conducted by an impartial person or

entity in accordance with §457.1150; (b) review decisions are timely in accordance with §457.1160; (c) review decisions are written; and (d) applicants and enrollees have an opportunity to: (1) represent themselves or have representatives of their choosing in the review process; (2) review their files and other applicable information relevant to the review of the decision; (3) fully participate in the review process, whether the review is conducted in person or in writing, including by presenting supplemental information during the review process; and (4) receive continued enrollment in accordance with §457.1170.

Comment: Two commenters noted that §457.361(c) establishes that notices of eligibility decisions must include information about the right of applicants to request a "hearing." Proposed §457.365, on the other hand, requires States to provide enrollees in separate child health programs with an opportunity to file "grievances and appeals" for denial, suspension, or termination of eligibility. These commenters expressed that the multiple reviews suggested by both these provisions of the proposed rule have the potential to create unnecessary administrative expenses for the State and to confuse consumers.

One of these commenters agreed that an applicant should receive an explanation, preferably in writing, if an application is denied. This notice is particularly important when the State

uses a variety of “helpers,” such as community organizations or other program staff, to assist in the enrollment process. In such situations, the commenter believed that opportunities for misinformation or miscommunication arise. For Medicaid programs, the commenter noted the word “hearing” is used to mean the entire State fair hearing process, which is a formal and often lengthy procedure. For separate child health programs, however, a much simpler process, such as review by a senior staff member, is appropriate according to this commenter, given that there is no individual entitlement to benefits under title XXI. This commenter therefore recommended that §457.361(c) be amended to make it clear that separate child health programs need not employ the Medicaid hearings process and that the State should provide an opportunity for review of such decisions that need not take the form of a hearing.

Response: We recognize that we may have created confusion in using different terminology in §§457.361(c) and 457.365. We therefore clarified the review process that will be applicable to adverse eligibility matters in §457.1140 of the final regulation.

We appreciate the commenter’s concern that certain enrollee protections may create an additional administrative expense for some States. However, on balance, the importance of ensuring an enrollee’s basic right to a fair and efficient decision regarding

eligibility for health benefits coverage justifies the administrative expenses that may be incurred. We note, furthermore, that these final regulations accord States broad flexibility to design review processes that operate efficiently without undue administrative costs. We also appreciate the support for the requirement that notice must be provided in writing.

As for the concerns about the mechanics of the review process, States with separate child health programs do not have to use the Medicaid fair hearing process as the mechanism for review of adverse eligibility and enrollment matters. While an opportunity for review of such matters is required, we left it to the States' discretion to develop the details of the review process for their separate programs, provided the process meets the minimum guidelines set forth in §§457.1140, 457.1150(a), 457.1160(a), 457.1170, and 457.1180.

Comment: One commenter asked that HCFA clarify what kinds of procedures will be necessary if a State does not elect to use its Medicaid program or does not have existing State law. One commenter expressed their view that the language of proposed §457.985 could be interpreted to mean that States without existing State laws requiring internal and external review procedures need not establish any procedures for children

enrolled in SCHIP. One commenter stated their view that a choice between Medicaid and State insurance practices is appropriate for issues other than eligibility and disenrollment determinations.

Response: We agree with the comment that our proposed rule could leave children in some States without access to a review process. Since State law varies and some States do not have applicable State laws, in order to assure some minimum standard of protections for all children, we elected to adopt in §457.1140 minimum standards for conducting reviews of matters identified in §457.1130. In addition, under §§457.1130(b) and 457.1150(b) of this final regulation, a State is required to ensure that enrollees have the opportunity for an external review of certain health services matters, regardless of whether external review is required under existing State law. Internal reviews are not required by these regulations.

! Impartial Review §457.1150 (proposed §457.985(b))

We proposed under §457.985(d) that States must establish and maintain written procedures for addressing grievances and appeal requests, including processes for internal review by the contractor and external review by an independent entity or the State agency. We proposed that these procedures must comply with State-specific grievance and appeal requirements currently in

effect for health insurance issuers (as defined in section 2791(b) of the Public Health Service Act) in the State.

Comment: One commenter recommended the language at §457.985(b) be amended to read "..process for internal review by the contractor and *independent* external review by the State agency.." This commenter noted it has established a strong independent review process through the State insurance agency. The commenter said that the term "independent entity" when used to describe an external review can be interpreted to mean an organization separate from the health plan, but chosen by the plan to do the reviews. The commenter noted that such an arrangement is a clear conflict of interest and indicated that the independence of reviewers can be best assured if the review goes through a neutral State agency. The commenter did not support the NAIC's Health Carrier External Review Model Act.

Response: We appreciate the concern related to the independence of external reviews and have made some modifications to clarify and emphasize the need for an impartial review. To afford States the greatest flexibility in how they implement their external review process, we did not change the language to allow only for external review by a State agency. Consistent with applicable State law, States may choose the entity that will provide external review.

However, under §457.1150(b), with respect to an external review of health services matters, we did specify that the external review must be independent and conducted by the State or a contractor other than the contractor responsible for the matter subject to external review. To the extent that a State relies on a contractor to conduct such reviews, we expect that States will closely monitor the review process to assure that enrollees are in fact receiving an independent review of their case. We also encourage community organizations and advocates to work closely with families to assist them in navigating the process and to assist the State in identifying issues related to impartiality or conflicts of interest if they arise. We would also like to note that in the review of eligibility and enrollment matters, we require under §457.1150(a) that a review must be conducted by an impartial person or entity who has not been directly involved in the matter under review.

Comment: One commenter expressed the view that the automatic placement of adverse decisions on the docket of a State fair hearing system is critical to ensuring that the rights of enrollees are fully vindicated, given that the State hearing system is the first time the enrollees receive an independent review. This commenter believed the burden placed on the fair hearing system would not outweigh the Constitutional deficiency

of not requiring an automatic filing for a fair hearing after an adverse decision by a non-impartial decision maker. This commenter said that due process concerns are significant, and that enrollees may not truly comprehend that they have a right to an external review despite the best efforts at notice on the part of a State/contractor and assuming they understood the notice of their rights. The commenter believed that automatic referral would reduce these problems, improve public perception about health care decisions given the review by an impartial decision maker, and improve the overall quality of care by encouraging correct treatment decisions at the outset.

The commenter noted that the number of cases proceeding through the State fair hearing process, even with automatic referral, may not be substantial or costly. According to the commenter, in Medicare where automatic referral occurs, the cost is generally less than $300 per case. In 1997, automatic referral resulted in only 1.65 cases per 1000 managed care enrolles. Yet, this commenter stated, access to an outside impartial review is clearly significant for enrollees. The commenter pointed to a Kaiser Family Foundation study on State external review laws that found almost 50 percent of cases considered through an external appeals review overturned the managed care organization’s initial decisions. The commenter

noted that while States have financial concerns in maintaining a streamlined external review process, such concerns should not overrule an enrollee's right to due process.

Response: As noted above, States do not need to use the State fair hearing process as the independent external review process required under §§457.1130(b) and 457.1150(b). External review can be done either by a State agency or a contractor other than the contractor responsible for the matter subject to external review. While we appreciate the commenter's concerns, we elected not to require States with separate child health programs to ensure the automatic referral of adverse decisions to external review. We did, however, adopt minimum procedural protections related to the right to an independent external review in certain situations, consistent with the requirements of due process.

We acknowledge the important information contained within the study cited by the commenter relating to the minimal administrative cost of automatic referral. Given the low cost of such a process, and the added protections and accountability it can provide in some circumstances, we encourage States to consider this option carefully when establishing their review process.

! Time frames §457.1160 (proposed §§457.361(c), 457.985(b) and 457.995(g)(2))

In proposed §457.985(b) and §457.995(g), respectively, we required that "resolution of grievances and appeal requests will be completed within a reasonable amount of time" and that "grievances and appeals must be conducted and resolved in a timely manner that is consistent with the standard health insurance practices in the State in accordance with **§**457.985." In proposed **§**457.361(c), we provided that "the State must send each applicant a written notice of the decision on the application and, if eligibility is denied or terminated, the specific reason or reasons for the action and an explanation of the right to request a hearing within a reasonable time."

Comment: Several commenters noted that the regulation should require that grievances and appeals be decided in a timely fashion. Several commenters asserted that if HCFA decides to maintain its proposed policy on grievances and appeals, strict minimal timelines should be incorporated to ensure that grievances and appeals are conducted in an expedited manner. A different commenter, representing providers, noted that it saw no reason why providers should not be expected to respond within seven days to a request for treatment. That commenter noted that if a State/contractor denied such a request, an enrollee would

not receive any new benefits until the final resolution of the grievance process. A State/contractor could request an extension if it could show the extension would be in the enrollee's best interest. The commenter also believed that HCFA should establish minimum requirements for an expedited procedure to meet the needs of enrolles with severe medical conditions.

This commenter also suggested a requirement of 14 days for a response to a standard grievance. Two commenters acknowledged that suggested time frames are different from the 30 day time frames in Medicare+Choice and Medicaid managed care, but argued that SCHIP enrollees do not have the opportunity to get services elsewhere while they are waiting for the appeal to be resolved. One commenter also noted that when Medicaid and SCHIP individuals are denied treatment, they often have no other recourse except the proposed grievance process. They recommended that HCFA reduce the standard resolution time frame in Medicaid managed care from 30 to 14 days. A different commenter recommended providing for an accelerated process where there is an initial denial of services that poses the risk of serious medical harm.

Several commenters recommended HCFA define maximum time frames, and one commenter recommended HCFA define a "reasonable" time period and indicate what maximum time frame would still meet the "reasonable" requirement. This second commenter also

believed that a lengthy grievance process might be held to violate an enrollee's due process rights. The commenter recommended a maximum time frame of fourteen days for responding to a standard grievance, which may be to review a provider's decision not to provide requested items or services, or to review a provider's decision to deny, suspend, or terminate eligibility, reduce or deny benefits, or disenroll the enrollee for failure to pay cost sharing. The commenter noted that, in many cases, the State/contractor will have an established policy and will not need the full fourteen days. This commenter also noted that even in cases which involve an assessment of an individual's condition, fourteen days is ample time. The commenter advocated that States be allowed to set a time frame of less than fourteen days. The commenter noted that a State/subcontractor does not necessarily save money by delaying resolution of a grievance, because the State remains financially responsible for the care and may have to reimburse the family for expenses incurred prior to enrollment. In certain cases, it might cost the State/subcontractor more to delay treatment because the treatment ultimately required might cost more than the initial requested treatment.

Response: As reflected in the proposed regulation, we agree that a review process should be completed in a timely fashion

and, as reflected in the final regulation, that there is a need for minimum timeliness standards. As in the proposed regulation, in §457.340(c) of this final regulation, we prescribed maximum time frames for eligibility determinations. In this final regulation, we also separately address the timeliness of review of eligibility and enrollment matters, and the timeliness of review of adverse health services matters. Under §457.1130(a), a State must ensure that an applicant or enrollee has an opportunity for review of a: (1) denial of eligibility; (2) failure to make a timely determination of eligibility; or (3) suspension or termination of enrollment, including disenrollment for failure to pay cost sharing. Under §457.1160(a), the State must complete the review of the matters described in §457.1130(a) within a reasonable amount of time. In order to ensure that delays in the review process do not cause a gap in coverage, under §457.1170, States are required to provide an opportunity for the continuation of enrollment pending the completion of review of a suspension or termination of enrollment, including a decision to disenroll for failure to pay cost sharing. We also require the State to consider the need for expedited review when there is an immediate need for health services. Under §457.1120 we require States to describe these time frames in their State plans.

In light of concern about the time frames for review of health services matters, we specified a time standard for the resolution of external reviews (and any internal review if available), including expedited time frames, in §457.1160(b). Health services matters subject to review include: (1) delay, denial, reduction, suspension, or termination of health services, in whole or in part, including a determination about the type or level of services; or (2) failure to approve, furnish, or provide payment for health services in a timely manner. Reviews must be completed in accordance with the medical needs of the patient. Under the standard time frame, a State must ensure that external review of a decision as described in §457.1150(b) is completed within 90 calendar days of the date an enrollee initially requests external review (or an internal review if available) of the decision. Under the expedited time frame, a State must ensure that internal review (if available), or external review as required by §457.1150(b), is completed within 72 hours of the time an enrollee initially requests a review if the enrollee's physician determines that operating under the standard time frame could seriously jeopardize the enrollee's life or health or ability to attain, maintain or regain maximum function. If the enrollee has access to internal and external review, then each level of review must be completed within 72 hours (for a possible

total of 144 hours). The State must provide an extension to the 72-hour period of up to 14 days if the enrollee requests such an extension. This provision for an expedited time frame reflects our agreement with the comments calling for an accelerated process if the passage of the standard time allowed for the process poses serious harm to the enrollee.

Comment: One commenter recommended that in order to ensure an enrollee's rights to obtain timely medical care, both the internal grievance process and the State fair hearing process should conclude within 90 days. They noted that current State fair hearing regulations require a State to complete the fair hearing within 90 days from the request for the hearing.

This commenter also stated the proposed regulations did not provide guidance on what happens if a State/contractor fails to meet its grievance and appeals procedures and recommended HCFA establish minimum standards to address noncompliance. The commenter said that even with standard health insurance practices, there is no guarantee that a State/contractor will comply in a timely fashion. The commenter recommended the approach of the Medicare+Choice regulations that provide that an managed care organization's failure to meet initial determination and reconsideration time frames is automatically considered an adverse decision that is referred to the next level of review.

This commenter advocated that HCFA adopt this policy in the SCHIP regulations as well. The commenter believed this position, coupled with minimum time frames, would best protect enrollees' rights without causing undue hardships on providers.

This commenter also recommended that HCFA should grant States the authority to impose monetary fines upon participating contractors for failure to meet time frames as a means to enforce compliance. The commenter recommended amending §457.935 to include language requiring States that contract with participating contractors to impose sanctions if the State determines that a participating contractor fails to provide medically necessary services that the participating contractor is required to provide, or fails to meet specified time frames.

Response: Under §457.1160(b)(1), we defined the standard time frame for the review of a health services matter. A State must ensure that external review, as described in §457.1150(b), is completed within 90 calendar days of the date an enrollee requests external review (or internal review if available). We expect that an enrollee will be provided notice of the outcome of the review within the 90-day time frame. As described above, the final regulations provide an opportunity for expedited review, under §457.1160(b)(2).

We do not see a need to create further compliance standards or enforcement mechanisms beyond those that have been already implemented pursuant to section 2106(d)(2) of the Act. This provision requires States to comply with the requirements under title XXI and allows HCFA to withhold funds from States in the case of substantial noncompliance with such requirements. It is within the State's discretion to determine whether to include in contracts monetary fines for failure to meet time frames as a means to enforce compliance with required time frames. States are, of course, required to administer their programs in accordance with the law and their State plans. At a minimum, therefore, States are responsible for monitoring the conduct of their contractors and ensuring that their conduct fully complies with these regulations and the State plan.

Comment: One commenter noted that the regulations do not make clear the relationship between the internal and external review processes. In most instances, State law requires exhaustion of the internal review process (as does the NAIC model) before a consumer can move to the external review. However, a number of States also include timelines and exceptions (for example, when the harm has already occurred) to ensure that this does not impede the process unnecessarily, and the commenter recommended that HCFA do the same. Another commenter expressed

that HCFA should prohibit States from requiring exhaustion of internal plan processes. If HCFA does not prohibit such a requirement, according to this commenter, it must include adequate safeguards so that plans do not benefit from delay at the enrollee's expense. Specifically, HCFA should require that States set strict timetables for review and determination, assure aid continuing pending a determination, and provide for expedited review when the failure to authorize a required level of treatment or to provide or continue a service jeopardizes the enrollee's health.

Another commenter noted that some States may require an enrollee to exhaust a plan's internal grievance procedures before allowing access to the State fair hearing process and believed these State practices may violate enrollee's due process rights. The commenter requested that we ensure that enrollees not be required to exhaust internal grievance procedures before accessing the State fair hearing process. The commenter was concerned that the internal grievance process does not provide impartial review. They noted that even under the proposed Medicaid managed care regulations, the individual conducting the internal review, while not familiar with the case file, is employed by the plan provider. According to this commenter, this individual has an inherent pecuniary interest to resolve the

grievance in favor of the State/contractor. Because the enrollee is effectively denied benefits until the process is complete, States/contractors have little incentive to resolve the grievances quickly. The commenter argued that if the enrollee is forced to exhaust the internal grievance process, the enrollee would be deprived of due process. The commenter recommended HCFA amend §457.985(b) to permit the enrollee to request a State fair hearing on a grievance at any time.

Response: It should be noted that the State fair hearing process is the process for external review under Medicaid managed care. While States have the option to use the Medicaid fair hearing process to satisfy the requirement for external review under this regulation, we do not require this process for separate child health programs. We also left to States the discretion to decide whether plans should be required to conduct an internal review and whether, if they do so, they should require exhaustion of internal plan processes before an enrollee could pursue an external review. Nonetheless, we believe it is important for enrollees to have certain minimum procedural protections consistent with due process and have therefore adopted minimum requirements and time frames for reviews. Under §§457.1130(b) and 457.1150(b), States must provide enrollees access to an external review of certain health services matters.

Pursuant to §457.1150(b), review decisions must be independent and made by the State or a contractor other than the contractor responsible for the matter subject to external review. While a State may require an enrollee to request and pursue an internal review, any procedures developed by the State or its contractors relating to internal review cannot interfere with the enrollee's right to complete the external review within 90 days from the data a review (either internal or external) is requested.

! Continuation of Enrollment §457.1170. (Proposed §457.985(c))

We received a number of comments urging us to require continuation of enrollment pending completion of the review.

Comment: Several commenters were particularly concerned that children receiving benefits under separate child health programs may be as poor as those who receive Medicaid in other States, and believed that States should therefore be required to continue assistance at pre-termination levels until an impartial review of a child's case is completed. Multiple commenters argued that even though the SCHIP statute does not include the same entitlement as Medicaid, constitutional due process may require minimal protections that are not included in the proposed rule. A few commenters underscored the need for due process protections in title XXI because of the lack of entitlement to

benefits under the program and recommended the Medicaid procedures. Other commenters echoed the specific suggestion that there be circumstances in which benefits continue for current recipients pending appeal.

One commenter specifically recommended that continuation of services pending appeal should occur in circumstances where termination or reduction of services poses serious medical harm and to provide for an accelerated process where there is an initial denial of services that pose such harm. Two commenters noted that continuation of benefits is especially important for enrollees terminated for failure to pay cost sharing or other financial contributions, which do not relate to an enrollee's actual eligibility for benefits. These commenters recommended that HCFA require that enrollees must affirmatively request termination of benefits. One commenter recommended the language at §457.985 be amended by adding: "Unless an enrollee affirmatively requests that items or services not be continued, the State/contractor must continue the enrollee's benefits until the issuance of the final grievance decision or State fair hearing decision."

Response: We appreciate the commenters' concerns about the need to protect children enrolled in separate child health programs who have very limited incomes and whose families have

little or no ability to pay for costly but necessary health services, and we have adopted provisions related to continuation of enrollment, as described below.

Section §457.1170 requires States to ensure the opportunity for continuation of enrollment pending review of termination or suspension of enrollment, including a decision to disenroll for failure to pay cost sharing. A State may limit the time period during which such coverage is provided by arranging for a prompt review of the eligibility or enrollment matter. However, not all such matters are subject to the continuation of coverage requirement; under **§**457.1130(c), a State is not required to provide an opportunity for review of such a matter if the sole basis for the decision is a provision in the State plan or in Federal or State law requiring an automatic change in eligibility, enrollment, or a change in coverage under the health benefits package that affects all applicants or enrollees or a group of applicants or enrollees without regard to their individual circumstances. Therefore, if the situation is such that the State is not required to provide an opportunity for review according to this regulation, then the State does not have to provide the opportunity for continuation of enrollment. We also note that the costs of providing continued benefits are not administrative costs subject to the 10 percent cap, regardless of

the outcome of the review. With respect to disenrollment due to failure to pay cost sharing, we have added a provision in §457.570(b) to ensure that the disenrollment process afford an enrollee the opportunity to show that the enrollee's family income has declined prior to disenrollment for nonpayment of cost-sharing charges. Finally, we note that services need not be continued pending a review of a health services matter, although, as described above, expedited review processes must be available when the physician or provider determines that the enrollee's life or health or ability to function will be jeopardized.

! Notice §457.1180 (proposed §§457.361(c), 457.902, 457.985(a), and 457.995(g)).

In the preamble to the proposed regulation at §457.985, we stated that a State should make available to families of targeted low-income children information about complaint, grievance, and fair hearing procedures. We proposed to require that the State and its "participating providers" give applicants and enrollees written notice of their right to file grievances and appeals. In proposed §457.361(c), we required that "the State must send each applicant a written notice of the decision on the application and, if eligibility is denied or terminated, the specific reasons or reasons for the action and an explanation of the right to request a hearing within a reasonable amount of time."

Comment: A commenter on §457.340 and §457.361 expressed strong support for the inclusion of rules setting minimum standards for procedural fairness, including the basic due process protections of opportunity to apply without delay, assistance in completing applications, required notices, and timely eligibility decisions. This commenter noted that notice is a basic due process right required by the U.S. Constitution under well-settled law whenever a citizen is denied a public benefit, and that the rules should specify that notice must be timely. The commenter also recommended that for current recipients, notice of an adverse action should be in advance of the action. In the commenter's view, the notice should inform people of the right to be accompanied by a representative as well as the right to appeal.

Another commenter on §457.340 suggested that rules should specify that notice of denial or adverse action must be timely and in advance of adverse action for current benefits, with benefits continuing through an appeal process, should an appeal be initiated. In this commenter's view, notice should be required to be timely and include information regarding the right to appeal and to be accompanied to the hearing by a representative.

Response: We appreciate the support for these standards, and the effort to establish rules that are consistent with due process requirements. We agree that notice should be timely and have added this to the language at §457.1180. As in the proposed regulation, the final regulation sets forth maximum time frames for eligibility determinations in §457.340(c). Additionally, in the case of redetermination of eligibility, under §457.340(d), the regulations require that in the case of a suspension or termination of eligibility, the State must provide sufficient and timely notice to enable the child's parent or caretaker to take any appropriate actions that may be required to ensure ongoing coverage. For example, if continued enrollment pending a review is allowed when a review is requested before enrollment is scheduled to end, notice of the action and the opportunity for review must be provided to the family with enough advance notice to allow the family to request the review and to keep their child enrolled pending review. Under §457.1160(a), a State must complete review of an eligibility or enrollment matter within a reasonable amount of time. In setting time frames, the State must consider the need for expedited decisions when there is an immediate need for health services. Additionally, under §457.1140(d)(2) we require that applicants and enrollees have a right to timely review of their files and other applicable

information relevant to the review of the decision. Under this final regulation, however, while States have discretion to determine the precise timing of the notices in light of their own administrative needs, the notice of the outcome of the review must be delivered within the prescribed overall time frames for review.

We addressed the issue of notice in §457.1180, in which we required States to ensure that applicants and enrollees are provided timely written notice of any determinations required to be subject to review under §457.1130 that includes the reasons for the determination; an explanation of applicable rights to review of that determination, the standard and expedited time frames for review, and the manner in which a review can be requested; and the circumstances under which enrollment may continue pending review. Section §457.340(d) cross references the notice requirements of §457.1180. Under §457.1140(d)(1) States must ensure that applicants and enrollees have an opportunity to represent themselves or have representatives of their choosing in the review process. As for continuation of enrollment, the regulations require States under §457.1170 to continue enrollment pending the completion of a review of a suspension or termination of enrollment including a decision to disenroll for failure to pay cost sharing.

Comment: One commenter requested clarification on the relationship of §457.361(c) to the requirement in §457.360(c). This commenter expressed a belief that every family should be notified of the status of each child's application and whether: (1) the application for enrollment in the separate child health program has been approved; (2) the application has been referred to Medicaid; or (3) the child had been found ineligible for both programs.

Response: The State must provide written notice of any determination of eligibility under §§457.340(d) and 457.1180. So, if the State determines that an applicant is ineligible for coverage under its separate child health program, the State must provide written notice of that determination. If the application is a joint Medicaid/SCHIP application, a State would then need to comply with Medicaid requirements in providing notice about an applicants eligibility for Medicaid. In the case of termination or suspension of eligibility, under §457.340(d), the regulations require that the State must provide sufficient notice to enable the child's parent or caretaker to take any appropriate actions that may be required to ensure ongoing coverage.

Comment: One commenter suggested that HCFA limit requirements that providers furnish notice to enrollees. According to this commenter, some States permit treating

providers and managed care plans to provide SCHIP applications and perform direct marketing activities, but some do not. In this commenter's view, providers in States that do not allow such involvement would have no opportunity to provide applicants with notices. This commenter also suggested that HCFA not require treating providers who serve SCHIP enrollees under a managed care contract to provide notice to enrollees. This commenter suggested that this would be more appropriately done by the managed care plan in the member information materials. Yet another commenter strongly supported the language in §457.985(a) requiring that participating providers, in addition to States, provide applicants and enrollees written notice of their right to file grievances. This commenter argued that it is important that applicants and enrollees have access to information about their grievance and appeal rights at the points of direct contact–which is most often the provider.

Response: In §457.1180, we specified the general content of the notice but left States the flexibility to determine who should provide the notice. We do not consider general statements of procedure in initial member information materials sufficient notice of the review process available for a particular determination.

Comment: One commenter noted that enrollees should be informed of their right to appeal any adverse decision to an independent body.

Response: We agree with the need for enrollee notification. Section 457.1180 requires timely notice of determinations subject to the review process specified in this regulation, including matters subject to external review by an independent entity.

! Application of Review Procedures where States Offer Premium Assistance for Group Health Plans §457.1190.

We note that under this final rule we use the term "premium assistance program" instead of "employer-sponsored insurance model" to describe a situation where a State pays part or all of the premiums for an enrollee or enrollees' group health insurance coverage or coverage under a group health plan. Our responses to comments referring to "employer-sponsored insurance models" reflect this change in terminology.

Comment: One commenter noted that for coverage provided under a premium assistance program, the State does not contract for services and is not in a position to dictate compliance with requirements included in §457.985.

Response: We acknowledge that States' SCHIP programs do not have direct authority over group health plans that may be providing coverage under premium assistance programs. At the

same time, there is no basis for providing children fewer procedural protections because they may be enrolled in a premium assistance program under SCHIP. In order to balance these concerns, the regulations provide States flexibility so that they may offer premium assistance through plans that do not meet the review standards set out in these regulations, as long as families are not required to enroll their children in these plans. Under §457.1190, a State that has a premium assistance program through which it provides coverage under a group health plan that does not meet the requirements of §§457.1130(b), 457.1140, 457.1150(b), 457.1160(b), and 457.1180 must give applicants and enrollees the option to obtain health benefits coverage through its direct coverage plan. The State must provide this option at initial enrollment and at each redetermination of eligibility.

Comment: One State expressed concern that the level of detail of the CBRR provisions in the proposed regulation inhibits States from developing effective premium payment systems for premium assistance programs. Another commenter noted that under premium assistance programs, there is no contractual mechanism through which to enforce requirements, given that the employer, not the State, contracts with the health plan. This commenter said that requiring States to apply these requirements under such

a model will mean that employer plans will never qualify for premium assistance. This commenter assumed that HCFA did not intend these requirements to apply to premium assistance programs, and recommended that HCFA clarify its position.

Response: While we appreciate the commenters' concern, States must comply with the requirements of this regulation regardless of whether coverage is provided through a group health plan. Under title XXI, the standards and protections apply to all children receiving SCHIP coverage, including children receiving SCHIP-funded coverage through group health plans. We do recognize that States to not have direct contractual relationships with premium assistance programs and accounted for this constraint in §457.1190.